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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,654	12/12/2003	Mark T. Muldoon	19596-0562 (45738-294842)	9327

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EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,654	MULDOON ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,11,13-15,17 and 18* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10, 11, 13, 15, 17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 2, 2006 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al. (US 2003/0022248).

Hsieh et al disclose a method for detecting rendered muscle in animal feedstuff. Hsieh et al disclose the use of an ELISA immunoassay in which sample suspected of comprising an analyte is combined with antibody (ligand). Hsieh et al disclose that the ligand can be detected by the addition of a second antibody that is labeled with an enzyme. Hsieh et al disclose wash steps to remove unbound complexes. Hsieh et al disclose measuring a signal generated and determining the presence of the analyte. Hsieh et al disclose the addition of antibodies in ELISA assay that have measurably lower binding affinity for one or more different species (taxonomic groups). Hsieh et al disclose that the ELISA can be in the form of an indirect ELISA , a sandwich ELISA or a competitive assay (paragraph 0030 & 0085). Hsieh et al disclose packing the components into a kit (paragraph 0030). Hsieh et al also disclose that the analyte of interest can be skeletal troponin.

With respect to the recitation "the amount of rendered animal byproduct detected by the method is about 0.005% to about 0.01%" as recited in the instant claims. Hsieh et al discloses that the detection limit of the mammalian and ruminant assays were between 0.3 and 2% and that if sandwich ELISA assays are performed the assay sensitivity could be enhanced such as

0.1% or less (paragraph 0085). Thus, the optimum percentage by weight and sensitivity can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Further, Hsieh et al discloses the same assays and reagents as recited in the instant claims and therefore would achieve the same results as recited by applicant. Thus, absent evidence to the contrary Hsieh et al would detect the percentages as recited.

6. Claims 2 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al in view of Voller (The Enzyme Linked Immunosorbent Assay, Diagnostic Horizons, Vol. 2, No. 1, 1978).

See above for teachings of Hsieh et al.

Hsieh et al differ from the instant invention in failing to specifically teach the ligand has a detectable label and a second ligand that is bound to at least one location on a solid phase.

Voller disclose ELISA assays for determining an analyte of interest. Voller disclose a double antibody sandwich ELISA for measuring an antigen of interest. Voller disclose an enzyme labeled antibody (ligand) for binding to the antigen and a second antibody (ligand) bound to a solid phase (p. 2). Voller discloses that the ELISA is a versatile tool and can be used for the quantitation of virtually any antibody and high molecular weight antigen.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a labeled ligand and immobilized ligand as taught by Voller in the method of Hsieh et al because Hsieh et al specifically teaches that the antibodies of Hsieh et al can be used double sandwich ELISA assays and further because Voller teaches that the ELISA is a versatile tool and can be used for the quantitation of virtually any antibody and high molecular weight antigen.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al in view of Schuurs et al (US 3,654,090) and further in view of Deger et al (US 5,437,981).

See above for teachings of Hsieh et al.

Hsieh et al differs from the instant invention in failing to teach an analyte analog that is bound to at least one location on a solid phase, wherein the ligand has a binding affinity for the analyte analog.

Schuurs et al disclose a method for the determination of a component of the antigen-antibody reaction. Schuurs et al disclose that the test system can be composed of antigen, labeled antibody (ligand) and immobilized antigen and that the labeled

antibody has binding affinity for the immobilized antigen (col 2, lines 66-69). Schuurs et al discloses that a good separation between the bound and free labeled component is essential (lines 43-44). Schuurs et al discloses that this assay format provides a method for assaying substances in very small quantities for a very high sensitivity (col 3, lines 15-18).

It would have been obvious to one or ordinary skill in the art at the time the invention was made to incorporate testing methods as taught by Schuurs et al into the method of Hsieh et al because Hsieh et all specifically teaches competitive assays can be used to determine the antigen of interest and further because Schuurs et al teaches that this assay format provides a method for assaying substances in very small quantities for a very high sensitivity.

Hsieh et al and Schuurs et al fail to teach the use of an analyte analog.

Deger et al. disclose competitive immunoassays used to determine an analyte of interest (col. 1). Deger et al disclose an immobilized analog (col 1, lines57-60). Deger et al disclose combining the sample containing the ligand (analyte) and antibody (ligand) with the immobilized analog.

It would have been obvious to one or ordinary skill in the art at the time the invention was made to substitute an immobilized analog as taught by Deger et al for the immobilized antigen of the modified method of Hsieh et al because Deger teaches it is known in the art to use analogs as reagents in competitive immunoassays. Further, the use of analyte analog in immunoassays is very well known in the art and therefore would be considered an obvious substitution for an immobilized antigen.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al in view of Jacobs et al (US 5,571,682) Guan et al (US 6,617,116)

See above for teachings of Hsieh et al.

Hsieh et al differs from the instant invention in failing to teach combining the sample and ligand with a labeled analyte analog and the ligand immobilized.

Jacobs et al disclose different types of immunoassays and teach that in competitive assay, a labeled analog of the target analyte to be determined is placed in competition with the analyte for a fixed amount of an appropriate, immobilized antibody (ligand) which can react with either the target analyte or a target analyte analog (col 1, lines 20-32). Jacobs et al disclose that this method provides for a means for determining how much target analyte is in the sample.

Guan et al disclose a competitive immunoassay for determining an analyte of interest. Guan et al disclose that analyte in sample competes with labeled analogue to the analyte, for a binding partner immobilized on a solid support (col 1, lines 37-40). Guan et al disclose that a competitive immunoassay provides a quantitative measure of analtye concentration (col 1, lines 46-48).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate competitive immunoassays as taught by Jacobs et al into the method of Hsieh et al because Hsieh et al specifically teaches that competitive assays can be used and further because Jacobs et al shows that this type of immunoassay provides for a means for determining how much target analyte is in the

sample. Further, the use of competitive immunoassays using labeled analyte analogs is very well known in the art.

It also would have been obvious to one of ordinary skill in the art to incorporate competitive immunoassays as taught by Guan et al into the method of Hsieh et al because Hsieh et al specifically teaches that competitive immunoassays can be used and further because Guan et al shows that this type of immunoassay provides a quantitative measure of analyte concentration. Further, the use of competitive immunoassays using labeled analyte analogs is very well known in the art.

9. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al in view of Ansfield US 5,910,446).

See above for teachings of Hsieh et al.

Hsieh et al differ from the instant invention in failing to teach the analyte is a component of meat and bone meal.

Ansfield discloses immunoassays to detect ruminant proteins in rendered animal materials . Ansfield discloses ELISA systems to determine an analyte of interest (col 3, lines 19-26). Ansfield discloses combining the sample and reagents and detecting a signal of the labeled antibodies bound to the protein. Ansfield discloses that the sample can be meat and bone meal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to detect meat and bone meal proteins such as taught by Ansfield in the method of Hsieh et al because Hsieh et al teaches the detection of rendered animal tissues in animal feed and teaches that the detection of undeclared exogenous

meat is important to comply with the animal feed regulation and Ansfield teaches detecting proteins in meat and bone meal. Further, Hsieh et al disclose that ELISA's can be used with meat and bone meals (para. 0085). Therefore, one of ordinary skill in the art would have a reasonable expectation of success detecting proteins found in meat and bone meal using the method of Hsieh et al.

10. Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al. (US 2003/0022248) in view of Thorn et al (US 2003/0083255).

See above for teachings of Hsieh et al.

Hsieh et al differ from the instant invention in failing to specifically teach the analyte is a component of cartilage.

Thorn et al disclose that Troponin I is a component of cartilage (a connective tissue) (paragraph 0034 & 0154).

It would have been obvious to one of ordinary skill in the art that the skeletal troponin as taught by Hsieh et al is a component of cartilage because Thorn et al teaches that Troponin I is a component of cartilage.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al in view of Radziejewski et al (US 6,022,694).

See above for teachings of Hsieh et al.

Hsieh et al differ from the instant invention in failing to teach the analyte is Type II collagen.

Radziejewski et al disclose assays for detecting Type II collagens in a sample (col 21). Radziejewski et al discloses that ligand binding assays are useful in

determining the presence and concentration of ligands in food products (col 2). Radziejewski et al disclose that using such assays to determine the presence and concentration of specific analytes has significantly improved medical diagnosis.

It would have been obvious to one or ordinary skill in the art at the time the invention was made to incorporate assays to detect Type II collagen as taught by Radziejewski et al into the method of Hsieh et al because Hsieh et al teach that the accurate labeling of meat products is mandated and monitored by the United States Department of Agriculture as well as by state and local governments (paragraph 0004) and controls to prevent the spread of BSE have prohibited the use of certain animal proteins in feed , requiring accurate analytical methods for detecting prohibited material in feed stuffs (para. 0012). Therefore, one of ordinary skill in the art would test a sample for components in order to accurately label the product. Further, Radziejewski et al discloses that ligand binding assays are useful in determining the presence and concentration of ligands in food products (col 2). Radziejewski et al disclose that using such assays to determine the presence and concentration of specific analytes has significantly improved medical diagnosis. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating binding assays for Type II collagen in the method of Hsieh et al.

12. Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsieh et al. (US 2003/0022248) in view of Foster et al (US 4,444,879).

See above for teachings of Hsieh et al.

Hsieh et al differ from the instant invention in failing to teach the kit contains instructions.

Foster et al disclose packing components and instructions for performing a method into a kit (col 15, lines 11-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate instructions as taught by Foster et al into the kit of Hsieh et al. because Foster et al teaches packing components and instructions for performing a method into a kit. Further, the kit would provide guidance and make it more facile and convenient for the test operator.

With respect to claim 18 Hsieh et al discloses that the detection limit of the mammalian and ruminant assays were between 0.3 and 2% and that if sandwich ELISA assays are performed the assay sensitivity could be enhanced such as 0.1% or less. Therefore, Hsieh et al and Foster reads on the instantly recited claims. Further, Hsieh et al disclose the same reagents as recited and therefore would achieve the same results.

Response to Arguments

13. Applicant's arguments with respect to claims 1-8, 10, 11, 13-15, 17 and 18 have been considered but are moot in view of the new ground(s) of rejection.

See above for the rejections.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
May 17, 2006

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05/25/06